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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,566	07/28/2000	Jonathan L. Goodwin	ATA-286	2331

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BOSTON, MA 02109

EXAMINER

BUI, VY Q

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 12/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/627,566

Applicant(s)

GOODWIN ET AL.

Examiner

Vy Q. Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -- as

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 13.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by DAVILA et al (6,296,661).

As to claims 1-2, DAVILA (Fig. 6; column 5, lines 3-9; claim 6) discloses stent-graft combination 50 of stent 60 and graft 70 of an expanded PTFE material, which has an average IND greater than 100 microns. Graft 70 extending along the interior of stent 60 has ends 72 and 74. Ends 72 and 74 are folded over and bonded to stent 60 to form outer cover 73/75. Because DAVILA stent-graft combination 50 includes all structural limitations as recited in the claims, inherently, DAVILA stent-graft combination 50 would also require a deployment pressure less than 10 atmospheres as recited in claim 1 of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over BANAS et al (6,124,523) in view of DAVILA et al (6,296,661).

As to claims 1 and 4, BANAS (Fig. 1, 1A, 2; column 1, lines 4-15; column 7, lines 12-17; claim 7) discloses a stent-graft implant comprising stent 22 sandwiched between inner cover 24 and outer cover 26 of expanded PTFE, inner cover 24 and outer cover 26 (each of a predetermined thickness) extend substantially along the entire length of the stent 22. BANAS does not disclose the expanded PTFE having IND of more than 100 microns. However, DAVILA (Figs. 6-7; claim 6) discloses a stent-graft implant comprising stent 60 sandwiched in graft material 70 of IND greater than 100 microns to allow a migration of cells to facilitate a more stable neointima on the surface of the stent-graft implant (DAVILA: column 8, lines 62-65). In view of DAVILA's teaching, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to provide ePTFE of IND greater than 100 microns for the BANAS's inner cover 24 and outer cover 26 as this configuration of the inner and outer covers would facilitate forming of a more stable neointima on the surface of the BANAS's stent-graft implant. The fact that the Applicants use the cover/graft having IND >100 microns in the present stent-graft device as claimed for a different purpose (to reduce a deployment pressure necessary to expand the stent) from DAVILA (to allow for the migration of cells to facilitate a more stable neointima on the surface of the stent-graft device) does not alter the conclusion that the cover/graft as claimed would be prima facie obvious from the cover/graft disclosed in the DAVILA reference." In re Lintner, 173 USPQ 560. In addition, even though BANAS and DAVILA do not disclose graft material having IND of greater 100 microns to reduce a deployment pressure necessary to expand the stent-graft combination to less than 10 atmospheres, since every structural limitation as recited in the claims is included by the combination stent-graft of BANAS and DAVILA (stent and cover/graft having IND greater than 100 microns), inherently, the stent-graft combination of BANAS and DAVILA would require a deployment pressure less than 10 atmospheres.

As to claim 2, DAVILA (Fig. 6; column 5, lines 3-10) discloses inner cover/graft 70 being folded at two ends of stent 60 over the outer surface of stent 60 to form outer cover and bonded the cover/graft 70 to stent 60 so as to fix the cover/graft 70 to stent 60 and avoid separation of the cover/graft 70 from stent 60 during stent-graft manufacturing and/or deployment process and also prevent the graft/cover 70 from coming off and draping into a vessel lumen (column 9, lines 40-51, DAVILA).

As to claim 3, DAVILA (Fig. 6; column 5, lines 3-10) shows a first portion of the inner cover 70 folded over the outer surface of the stent 60 and a second portion of the inner cover 70 folded over the outer surface of the stent 60. DAVILA does not show the second portion of the inner cover 70 folded over the first portion of the inner cover 70 as claimed. Naturally, applying multiple folding layers over an object would provide extra securement between the folding layers and the object. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to fold the second portion of the inner cover 70 over the first portion of the inner cover 70 as this configuration would provide extra bonding/securement between cover 70 and stent 60 and surely avoid separation between stent 60 and graft 70 during manufacturing and/or deployment (column 9, lines 40-51, DAVILA). Beside the benefit of providing an extra securement between stent 60 and graft 70 as discussed above, the second folding of the second portion of the graft 70 over the first portion of graft 70 does not appear to provide any significant improvement for the device's performance and therefore would not be considered as an significant novel feature of the instant application over the reference.

2. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over BANAS et al (6,124,523) in view of DAVILA et al (6,296,661) and further in view of LEWIS et (5,993,489).

As to claims 6 and 9, BANAS and DAVILA disclose substantially all limitations as recited in the claims, except for the thickness of the cover being at least about .008 inch (or 0.2032 mm). LEWIS (abstract, lines 1-7; column 2, line 9-31) discloses an ePTFE vascular graft having radial thickness of about 0.25 mm or 0.010" and a GORE-TEX vascular graft material of radial thickness about 0.4 mm or 0.016". It would have been obvious one of ordinary skill in the art at the time of the invention was made to make BANAS's cover of radial thickness at least 0.008" (or 0.20 mm) as the process to make

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ePTFE of radial thickness at least 0.008" (0.20 mm) is well-known. Notice that BANAS and DAVILA do not disclose graft material having IND of greater 100 microns to reduce a deployment pressure necessary to expand the stent-graft combination to less than 10 atmospheres. However, since every structural limitation as recited in the claims (for example, cover or graft has IND >100 microns) is included by the combination stent-graft of BANAS and DAVILA (stent and cover/graft having IND greater than 100 microns) as discussed earlier in the rejection of claims 1 and 4, inherently, the stent-graft combination of BANAS and DAVILA would require a deployment pressure less than 10 atmospheres. The fact that the Applicants use the cover/graft having IND > 100 microns in the present stent-graft device as claimed for a different purpose (to reduce a deployment pressure necessary to expand the stent) from DAVILA graft material having IND > 100 microns (to allow for the migration of cells to facilitate a more stable neo-intima on the surface of the stent-graft device) does not alter the conclusion that the cover/graft as claimed would be prima facie obvious from the cover/graft disclosed in the DAVILA reference." In re Lintner, 173 USPQ 560.

As to claim 7, DAVILA (Fig. 6; column 5, lines 3-10) discloses inner cover/graft 70 being folded at two ends of stent 60 over the outer surface of stent 60 to form outer cover and bonded the cover/graft 70 to stent 60 so as to fix the cover/graft 70 to stent 60 and avoid separation of the cover/graft 70 from stent 60 during stent-graft manufacturing and/or deployment process and also prevent the graft/cover 70 from coming off and draping into a vessel lumen (column 9, lines 40-51, DAVILA).

As to claim 8, DAVILA (Fig. 6; column 5, lines 3-10) shows a first portion of the inner cover 70 folded over the outer surface of the stent 60 and a second portion of the inner cover 70 folded over the outer surface of the stent 60. DAVILA does not show the second portion of the inner cover 70 folded over the first portion of the inner cover 70. Naturally, applying multiple folding layers over an object would provide extra securement between the folding layers and the object. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to fold the second portion of the inner cover 70 over the first portion of the inner cover 70 as this configuration would provide extra bonding between cover 70 and stent 60 and surely avoid separation between stent 60 and graft 70 during manufacturing and/or

deployment (column 9, lines 40-51, DAVILA). Beside the benefit of providing an extra securement between stent 60 and graft 70 as discussed above, the second folding of the second portion of the graft 70 does not appear to provide any significant improvement for the device's performance and therefore would not be considered as an significant novel feature of the instant application over the reference.

Response to Amendment

The Applicants' "Remarks" October 9, 2002 has been carefully considered but is moot in view of new rejections presented in this "Office Action".

Basically, the Applicants contend that the teaching of EDWIN (6,039,755) about a graft material having IND in a range of maximum about 33 microns does not appear closely related to the graft material in the instant application, which has an IND being greater than 100 microns. The EDWIN reference is not applicable in the new rejections as presented in this "Office Action".

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is (703) 306-1382 and whose email address is vy.bui@uspto.gov.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano, can be reached at (703) 308-2496. The fax number for this Unit is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at (703) 308-0858



VQB

December 24, 2002.